



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room -WO66-G609
Silver Spring, MD 20993-0002

Alma Lasers, Inc.
% Ms. Tatiana Epstein
Vice President, QA and RA
485 Half Day Road, Suite 100
Buffalo Grove, Illinois 60089

JAN 14 2011

Re: K103501

Trade/Device Name: Alma Lasers Pixel CO₂™ Laser System,
Delivery Devices and Accessories

Regulation Number: 21 CFR 886.4390

Regulation Name: Ophthalmic laser

Regulatory Class: Class II

Product Code: HQF

Dated: January 04, 2011

Received: January 07, 2011

Dear Ms. Epstein:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

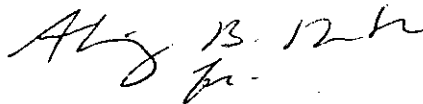
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson".

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
And Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K103501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use:

The Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: aesthetic surgery (dermatology and plastic surgery), podiatry, gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee).

The Alma Lasers Pixel CO2™ Laser System is cleared for use for the particular indications as follows:

Dermatology & Plastic Surgery

The ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of:

- laser skin resurfacing
- laser derm-abrasion
- laser burn debridement.

Laser skin resurfacing (ablation and/or vaporization) for the treatment of:

- wrinkles, rhytids, and furrows (including fines lines and texture irregularities)

Clinical literature demonstrates that skin resurfacing of wrinkles, rhytids, and furrows with CO₂ laser increases the amount of sub-epidermal collagen.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for me
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103501Page 1 of 10

Indications for Use Statement

510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dermatology & Plastic Surgery, continued

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart, and verruca seborrheica;
- vermillionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- chelitis, including actinic chelitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- tattoos;
- telangiectasia;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- superficial pigmented lesions;
- adenosebaceous hypertrophy or sebaceous hyperplasia;
- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K103501Page 2 of 10

Indications for Use Statement510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dermatology & Plastic Surgery, continued

- nevi, including spider, epidermal and protruding;
- neurofibromas;
- laser de-epithelialization;
- tricoepitheliomas;
- xanthelasma palpebrarum;
- syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrhoecae vulgares, including paronychia, periungal, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.


Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)
(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K10 3501

Page 3 of 10

Indications for Use Statement

510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal, and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychia, periungal, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- choanal atresia,
- leukoplakia, including oral, larynx, uvula, palatal, upper-lateral-pharyngeal-tissue; _____
- nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages;
- lymphangioma removal;
- removal of vocal cord/fold nodules, polyps and cysts;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for ntm
(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K103501Page 4 of 10

Indications for Use Statement

510(k) Number (if known): K10 3501

Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Otolaryngology (ENT), continued

- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)];
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas; (oral);
- stapedotomy/stapedectomy;
- acoustic neuroma in the ear;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy and turbinate reduction/ablation);
- septal spur ablation/reduction and septoplasty;
- partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil K. Dyer for xxx
(Division Sign-Off)

Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K103501

Page 5 of 10

Indications for Use Statement510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- leukoplakia (vulvar dystrophies);
- incision and drainage (I&D) of Bartholin's and nubuthian cysts;
- herpes vaporization;
- urethral caruncle vaporization;
- cervical dysplasia;
- benign and malignant tumors;
- hemangiomas.

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;
- salpingostomy;
- oophorectomy/ovariectomy;
- fimbrioplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Michael J. Doherty for me
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K10-3501Page 6 of 10

Indications for Use Statement510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

GYN Laparoscopy, continued

- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy.

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of:

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- arteriovenous malformation;
- pituitary gland tumors (transphenoidal approach).

Spinal Cord

- incision/excision and vaporization of benign and malignant tumors and cysts;
- intra- and extradural lesions;
- laminectomy/ laminotomy/ microdiscectomy.

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K103501Page 7 of 10

Indications for Use Statement510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- menisectomy;
- chondromalacia;
- chondroplasty;
- ligament release (lateral and other);
- excision of plica;
- partial synovectomy.

General

- debridement of traumatic wounds;
- debridement of decubitus and diabetic ulcers;
- microsurgery;
- artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- mastectomy;
- debridement of burns;
- rectal and anal hemorrhoidectomy;
- breast biopsy;

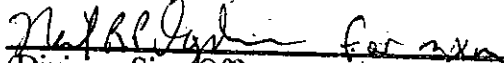
Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K10-3501Page 8 of 10

Indications for Use Statement

510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

General/Thoracic Surgery, continued

- reduction mammoplasty;
- cytorreduction for metastatic disease;
- laparotomy and laparoscopic applications;
- mediastinal and thoracic lesions and abnormalities;
- skin tag vaporization;
- atheroma;
- cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- pilonidal cyst removal and repair;
- abscesses;
- other soft tissue applications.

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- gingivectomy- removal of hyperplasias;
- gingivoplasty;
- incisional and excisional biopsy;
- treatment of ulcerous lesions, including aphthous ulcers;
- incision of infection when used with antibiotic therapy;
- frenectomy (frenum release);
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;

Prescription Use ☒
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)


(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K10 3501Page 9 of 10

Indications for Use Statement510(k) Number (if known): K10 3501Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dental/Oral Surgery, continued

- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- leukoplakia;
- partial glossectomy;
- periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- phimosis
- erythroplasia.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Nat. R. Dgale for max
(Division Sign-Off)Division of Surgical, Orthopedic,
and Restorative Devices510(k) Number K103501Page 10 of 10

**Appendix 7– 510(k) Summary for the Alma Lasers Pixel CO₂TM Laser System,
Delivery Devices and Accessories**

Summary Preparation Date: November 24, 2010

• **General Information**

<u>Sponsor/ 510(k) Owner</u>	<u>Sponsor</u>
<u>Address and Establishment Registration #</u>	Alma Lasers, Inc. 485 Half Day Rd. Suite No. 100 Buffalo Grove, IL 60089, USA FDA Registration #: 3004167969
	Tatiana Epstein VP QA&RA Alma Lasers, Inc.
	Telephone: (224) 377-2011 Facsimile: (224) 377-2050 Email: tatianae@almalasers.com
<u>Contact Person:</u>	<u>Main Contact:</u>
	Tatiana Epstein VP QA&RA Alma Lasers, Inc.
	Telephone: (224) 377-2011 Facsimile: (224) 377-2050 Email: tatianae@almalasers.com
	<u>Secondary Contact:</u>
	Avi Farbstein EVP and GM North America Alma Lasers, Inc.
	Telephone: (224) 377-2011 Facsimile: (224) 377-2050 Email: Avi.Farbstein@almalasers.com

• **Names**

Device Names: Alma Lasers Pixel CO₂TM Laser System, Delivery
Devices and Accessories

Primary Classification Names: Laser Instrument, Surgical, Powered; GEX

• **Predicate Devices**

Alma Lasers ThermoXELTM CO₂ Laser System and Delivery Device Accessories
(K080463), cleared 07/23/2008

• **Product Description**

The Alma Lasers Pixel CO₂TM Laser System, Delivery Devices and Accessories are used to deliver light energy and are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties, including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee) , general and thoracic surgery (including open and endoscopic), oral surgery and genitourinary surgery.

The Alma Lasers Pixel CO₂TM CO₂ Laser System consists of the following major components (refer to **Error! Reference source not found.**):

6. Laser system console (containing the optical bench assembly and laser, the microcontroller control electronics and system software, the high voltage power supply, the laser cooling system, the compressed air-purge system, and the service panel)

7. LCD control panel with touch-screen technology
8. 7-joint articulated arm
9. Footswitch
10. Delivery Device Handpieces:
 - Focusing handpieces
 - Pixel handpieces

- **Indications for Use**

The Alma Lasers Pixel CO₂™ Laser System, Delivery Device and Accessories are used to deliver light energy and are intended for use in surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in the medical specialties, including: aesthetic (dermatology and plastic surgery), podiatry, otolaryngology (ENT), gynecology, neurosurgery, orthopedics (soft tissue), arthroscopy (knee), general and thoracic surgery (including open and endoscopic), oral surgery and genitourinary surgery.

The intended use is identical to that previously cleared for the Alma Lasers ThermoXEL™ CO₂ Laser System and Delivery Device Accessories (K080463).

The Indications for Use statement can be found in Appendix 4.

- **Rationale for Substantial Equivalence**

The Alma Lasers Pixel CO₂™ Laser System, Delivery Device and Accessories has the following similarities to the previously cleared Alma Lasers ThermoXEL™ CO₂ Laser System and Delivery Device Accessories (K080463):

- Has the same intended use and indications for use,
- Uses the same operating principle (technology),
- Incorporates the same basic design,
- Incorporates the same materials,
- Is packaged using the same materials and processes.

In summary, the Alma Lasers Pixel CO₂™ Laser System, Delivery Device and Accessories is substantially equivalent to the predicate devices.

- **Safety and Effectiveness Information**

The review of the indications for use and technical characteristics provided demonstrates that the Alma Lasers Pixel CO₂™ Laser System, Delivery Device and Accessories is substantially equivalent to the predicate device.

- **Conclusion**

Alma Lasers Pixel CO₂™ Laser System, Delivery Device and Accessories was found to be substantially equivalent to the predicate Alma Lasers ThermoXEL™ CO₂ Laser System and Delivery Device Accessories (K080463).

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dermatology & Plastic Surgery, continued

Laser skin resurfacing (ablation and/or vaporization) of soft tissue for the reduction, removal, and/or treatment of:

- keratoses, including actinic and seborrheic keratosis, seborrhoecae vulgares, seborrheic wart, and verruca seborrheica;
- vermillionectomy of the lip;
- cutaneous horns;
- solar/actinic elastosis;
- cheilitis, including actinic cheilitis;
- lentigines, including lentigo maligna or Hutchinson's malignant freckle;
- uneven pigmentation/ dyschromia;
- acne scars;
- surgical scars;
- keloids including acne keloidalis nuchae;
- hemangiomas (including Buccal, port wine and pyogenic granulomas/granuloma pyogenicum/granuloma telangiectaticum);
- tattoos;
- telangiectasia;
- removal of small skin tumors, including periungual (Koenen) and subungual fibromas;
- superficial pigmented lesions;
- adenosebaceous hypertrophy or sebaceous hyperplasia;
- rhinophyma reduction;
- cutaneous papilloma (skin tags);
- milia;
- debridement of eczematous or infected skin;
- basal and squamous cell carcinoma, including keratoacanthomas, Bowen's disease (Erythroplasia of Queyrat), and Bowenoid Papulosis (BP) lesions;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dermatology & Plastic Surgery, continued

- nevi, including spider, epidermal and protruding;
- neurofibromas;
- laser de-epithelialization;
- tricoepitheliomas;
- xanthelasma palpebrarum;
- syringoma

Laser ablation, vaporization and /or excision for complete or partial nail matrixectomy.

Vaporization/coagulation of:

- benign/malignant vascular/avascular skin lesions;
- Moh's Surgery;
- Lipectomy;
- Verrucae and seborrhoecae vulgares, including paronychial, periungal, and subungual warts.

Laser incision and /or excision of soft tissue for the performance of upper and lower eyelid blepharoplasty.

Laser incision and /or excision of soft tissue for the creation of recipient sites for hair transplantation.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Podiatry

Laser ablation, vaporization and /or excision of soft tissue for the reduction, removal; and/or treatment of:

- verrucae vulgares/plantar (warts), including paronychia, periungual, and subungual warts;
- fungal nail treatment;
- porokeratoma ablation;
- ingrown nail treatment;
- neuromas/fibromas, including Morton's neuroma;
- debridement of ulcers;
- other soft tissue lesions.

Laser ablation, vaporization and /or excision in podiatry for complete or partial matrixectomy.

Otolaryngology (ENT)

Laser incision, excision, ablation and/or vaporization of soft tissue in otolaryngology the treatment of:

- choanal atresia,
- leukoplakia, including oral, larynx, uvula, palatal, upper lateral pharyngeal tissue;
- nasal obstruction;
- adult and juvenile papillomatosis polyps;
- polypectomy of nose and nasal passages;
- lymphangioma removal;
- removal of vocal cord/fold nodules, polyps and cysts;
- removal of recurrent papillomas in the oral cavity, nasal cavity, larynx, pharynx and trachea, including the uvula, palatal, upper lateral pharyngeal tissue, tongue and vocal cords;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Otolaryngology (ENT), continued

- laser/tumor surgery in the larynx, pharynx, nasal, ear and oral structures and tissue;
- Zenker's Diverticulum/pharyngoesophageal diverticulum [endoscopic laser-assisted esophagodiverticulostomy (ELAED)];
- stenosis, including subglottic stenosis;
- tonsillectomy (including tonsillar cryptolysis, neoplasma) and tonsil ablation/tonsillotomy;
- pulmonary bronchial and tracheal lesion removal;
- benign and malignant nodules, tumors and fibromas (larynx, pharynx, trachea, tracheobronchial/endobronchial);
- benign and malignant lesions and fibromas (nose and nasal passages);
- benign and malignant tumors and fibromas; (oral);
- stapedotomy/stapedectomy;
- acoustic neuroma in the ear;
- superficial lesions of the ear, including chondrodermatitis nodularis chronica helices/Winkler's disease;
- telangiectasia/hemangioma of larynx, pharynx and trachea (includes uvula, palatal or upper lateral pharyngeal tissue);
- cordectomy, cordotomy (for the treatment of vocal fold paralysis/vocal fold motion impairment), and cordal lesions of larynx, pharynx and trachea;
- myringotomy/tympanostomy (tympanic membrane fenestration);
- uvulopalatoplasty (LAUP, laser UPPP);
- turbinectomy and turbinate reduction/ablation);
- septal spur ablation/reduction and septoplasty;
- partial glossectomy;
- tumor resection on oral, subfacial and neck tissues;
- rhinophyma;
- verrucae vulgares (warts);
- gingivoplasty/gingivectomy.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Gynecology (GYN)

Laser incision, excision, ablation and/or vaporization and of soft tissue in gynecology (GYN) for the treatment of:

- conization of the cervix, including cervical intraepithelial neoplasia (CIN), vulvar and vaginal intraepithelial neoplasia (VIN, VAIN);
- condyloma acuminata, including cervical, genital, vulvar, perineal, and Bowen's disease, (Erythroplasia of Queyrat) and Bowenoid papulosa (BP) lesions;
- leukoplakia (vulvar dystrophies);
- incision and drainage (I&D) of Bartholin's and nubuthian cysts;
- herpes vaporization;
- urethral caruncle vaporization;
- cervical dysplasia;
- benign and malignant tumors;
- hemangiomas.

GYN Laparoscopy

Vaporization, incision, excision, ablation, or photocoagulation of soft tissue in endoscopic and laparoscopic surgery, including GYN laparoscopy, for treatment of:

- endometrial lesions, including ablation of endometriosis;
- excision/lysis of adhesions;
- salpingostomy;
- oophorectomy/ovariectomy;
- fimbrioplasty;
- metroplasty;
- microsurgery (tubal);
- uterine myomas and fibroids;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

GYN Laparoscopy, continued

- ovarian fibromas and follicle cysts;
- uterosacral ligament ablation;
- hysterectomy.

Neurosurgery

Laser incision, excision, ablation and/or vaporization and of soft tissue in neurosurgery for the treatment of:

Cranial

- posterior fossa tumors;
- peripheral neurectomy;
- benign and malignant tumors and cysts (e.g. gliomas, meningiomas (including basal tumors), acoustic neuromas, lipomas and large tumors);
- arteriovenous malformation;
- pituitary gland tumors (transphenoidal approach).

Spinal Cord

- incision/excision and vaporization of benign and malignant tumors and cysts;
- intra- and extradural lesions;
- laminectomy/ laminotomy/ microdiscectomy.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Orthopedics

Incision/excision and vaporization and of soft tissue in orthopedic surgery. Applications include:

Arthroscopy

- meniscectomy;
- chondromalacia;
- chondroplasty;
- ligament release (lateral and other);
- excision of plica;
- partial synovectomy.

General

- debridement of traumatic wounds;
- debridement of decubitus and diabetic ulcers;
- microsurgery;
- artificial joint revision;
- PMMA removal.

General/Thoracic Surgery

Incision, excision and vaporization and of soft tissue in general and thoracic surgery including endoscopic and open procedures. Applications include:

- debridement of decubitus ulcers, stasis, diabetic and other ulcers;
- mastectomy;
- debridement of burns;
- rectal and anal hemorrhoidectomy;
- breast biopsy;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

General/Thoracic Surgery, continued

- reduction mammoplasty;
- cytoreduction for metastatic disease;
- laparotomy and laparoscopic applications;
- mediastinal and thoracic lesions and abnormalities;
- skin tag vaporization;
- atheroma;
- cysts, including sebaceous cysts, pilar cysts, and mucous cysts of the lips;
- pilonidal cyst removal and repair;
- abscesses;
- other soft tissue applications.

Dental/Oral Surgery

Incision/excision and vaporization of soft tissue in dentistry and oral surgery. Applications include:

- gingivectomy- removal of hyperplasias;
- gingivoplasty;
- incisional and excisional biopsy;
- treatment of ulcerous lesions, including aphthous ulcers;
- incision of infection when used with antibiotic therapy;
- frenectomy (frenum release);
- excision and ablation of benign and malignant lesions;
- homeostasis;
- operculectomy;
- crown lengthening;

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Indications for Use Statement510(k) Number (if known): K10Device Name: Alma Lasers Pixel CO2™ Laser System, Delivery Devices and Accessories

Indications for Use - Continued from the previous page:

Dental/Oral Surgery, continued

- removal of soft tissue, cysts and tumors;
- oral cavity tumors and hemangiomas;
- abscesses;
- extraction site hemostasis;
- salivary gland pathologies;
- preprosthetic gum preparation;
- leukoplakia;
- partial glossectomy;
- periodontal gum resection.

Genitourinary

Incision/excision and vaporization and of soft tissue in genitourinary procedures. Applications include:

- benign and malignant lesions of external genitalia;
- condyloma;
- phimosis
- erythroplasia.

Prescription Use ✓
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use _____
(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)